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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,992	02/28/2005	Sudershan Kumar Arora	006420.00003	2784

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BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,992	ARORA ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11, drawn to an anticonvulsant pharmaceutical composition for nasal administration having binding affinities for the receptor sites viz. GABA-A agonist site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (Strychnine insensitive) site and Sodium channel (site 2) comprising an extract of the pericarp of the fruit of *S. trifoliatus*, comprising from 0.001 to 1.0 (%w/v) of hederagenin and pharmaceutically acceptable additives.

Group II, claims 12-14, drawn to a process for preparation of an extract containing 4 to 8% w/w of hederagenin comprising the steps of extraction of the pericarp of the fruit of *S. trifoliatus* with water or an alcohol or a mixture thereof at ambient to boiling temperature of 0.5 to 24 hours, lyophilization of the aqueous, alcoholic or aqueous alcoholic extract containing a mixture of saponins to give a lyophilized powder containing a mixture of saponins and reconstitution of the lyophilized extract in water to achieve a concentration of hederagenin between 0.001 to 1.0 (% w/v).

Group III, claim 15, drawn to a process for preparation of an anticonvulsant pharmaceutical composition comprising adding lyophilized aqueous extract of *S. trifoliatus* as claimed in claim 12 to a mixture of chlorobutanol and phenylethyl alcohol in water and sodium chloride to get a uniform dispersion, filtering, mixting above dispersion with dispersion of xanthan gum in purified water and adjusting the pH between 4.5 to 6.5.

Group IV, claim(s) 16 and 17, drawn to an extract according to Claim 1, which exhibits in vitro receptor binding affinity towards specific receptors like GABA-A agonistic site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (Strychnine insensitive) site and Sodium channel (site 2) which have mediatory role in anticonvulsant effect.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is drawn to an anticonvulsant pharmaceutical composition for nasal administration having binding affinities for the receptor sites viz. GABA-A agonist site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (Strychnine insensitive) site and Sodium channel (site 2) comprising an extract of the pericarp of the fruit of *S. trifoliatus*, comprising from 0.001 to 1.0 (%w/v) of hederagenin and pharmaceutically acceptable additives. The special technical feature of Group II is a process for preparation of an extract containing 4 to 8% w/w of hederagenin comprising the steps of extraction of the pericarp of the fruit of *S. trifoliatus* with water or an alcohol or a mixture thereof at ambient to boiling temperature of 0.5 to 24 hours, lyophilization of the aqueous, alcoholic or aqueous alcoholic extract containing a mixture of saponins to give a lyophilized powder containing a mixture of saponins and reconstitution of the lyophilized extract in water to achieve a concentration of hederagenin between 0.001 to 1.0 (% w/v), which is not required for Group I. The special technical feature of Group III is a process for preparation of an anticonvulsant pharmaceutical composition comprising adding lyophilized aqueous extract of *S. trifoliatus* as claimed in claim 12 to a mixture of chlorobutaol and phenylethyl alcohol in water and sodium chloride to get a uniform dispersion, filtering, mixting above dispersion with dispersion of xanthan gum in purified water and adjusting the pH between 4.5 to 6.5, which is not required for Group I. The special technical feature of Group IV is an extract according to Claim 1, which exhibits

in vitro receptor binding affinity towards specific receptors like GABA-A agonistic site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (Strychnine insensitive) site and Sodium channel (site 2) which have mediatory role in anticonvulsant effect, which is not required for Group I. Finally, Claim 1, at least, is anticipated by or obvious over Gupta et al. (CA2409051, 29.11.2001). Gupta teaches a pharmaceutical composition for treating migrane comprising of an extract of the pericarp of the fruit of *Sapindus trifoliatus* in an amount of 0.1 to 1.0 % w/v (See page 11, lines 1-14 and page 38, claim 1) and pharmaceutically acceptable additives in the form of nasal drops (See Abstract). Gupta further teaches that *Sapindus trifoliatus* inherently contains hedergenin (See page 11, lines 10-13). Gupta does not specifically teach a composition having binding affinities for the receptor sites viz. GABA-A agonist site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (Strychnine insensitive) site and Sodium channel (site 2) nor does Gupta specifically teach 0.001 to 1.0 (%w/v) of hederagenin present in the composition, however, the composition as taught by Gupta has the same functional effect as the composition claimed by Applicant. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so the invention lacks unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I:

Specie A: elect one form of extract from Claim 3.

Specie B: elect one agent from claim 5 or 6.

Specie C: elect one agent for adjusting the viscosity from Claim 7.

Specie D: elect one agent for adjusting the pH from Claim 8.

Specie E: elect one preservative agent from Claim 9.

Specie F: elect one nasal administration form from Claim 11.

Group II:

Specie A: elect one alcohol from Claim 14.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I:

Specie A: drawn to Claim 3.

Specie B: drawn to Claims 5-9.

Specie C: drawn to Claim 7.

Specie D: drawn to Claim 8.

Specie E: drawn to Claim 9.

Specie F: drawn to Claim 11.

Group II:

Specie A: drawn to Claim 14.

The following claim(s) are generic: 1, 2, 4, 10, 12, 13 and 15-17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The above species share no common core structure.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source,

all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
AU 1655

Amy L. Clark
March 21, 2006

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER